

**REMARKS**

Claims 18-20 and 37-38 are pending and under examination. Applicants have herein amended claims 18-20 and 37-38. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested, wherein claims 18-20 and 37-38 will still be pending and under examination.

**Title of the Invention**

The Examiner objected to the title, stating that the title of the invention is not descriptive.

In response, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended the title such that it now recites "Modified IL-2 Polypeptides."

**ATCC Information**

The Examiner objected to the specification, requesting that applicants update the ATCC address and provide the ATCC deposit number.

In response, applicants have amended the specification to reflect the current ATCC address and the ATCC number. A copy of the ATCC deposit receipt is attached hereto as **Exhibit C.**

**Claim 38**

The Examiner objected to claim 38, stating that it is informal in reciting "purified o homogeneity."

In response, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended claim 38 to recite "purified to homogeneity." Applicants contend that this amendment obviates the above objection and respectfully request that the Examiner reconsider and withdraw this ground of objection.

Rejection under 35 U.S.C. 112, first paragraph- written description

The Examiner rejected claims 18-20 and 37-38, alleging that they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventions had possession of the claimed invention at the time the application was filed.

In response, applicants respectfully traverse the Examiner's above rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended the claims. Claim 18 now recites "the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene." Claim 18 now provides a further structural feature that could distinguish compounds in the genus from others, i.e. that the gene encoding human interleukin-2 from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene. Hybridization under stringent wash conditions may be sufficient to meet the requirements of written description. *See Enzo Biochem v. Gen-Probe*, 63 U.S.P.Q.2d 1609, 1615-1616 (Fed. Cir. 2002); *See also* Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, &1, 66 Fed. Reg. 1099 (January 5, 2001). Applicants contend that hybridization of nucleic acids under stringent wash conditions provides the necessary structure so as to distinguish the genus of polypeptides encoded by these nucleic acids from others. Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 U.S.C. 112, first paragraph- enablement

The Examiner rejected claims 18-20 and 37-38, alleging that these claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, applicants respectfully traverse the Examiner's above rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended the claims. Claim 18 now recites "the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions

to a normal human interleukin-2 gene." Applicants contend that one skilled in the art would be able to distinguish the claimed polypeptides from others, e.g. they must be encoded by a gene which hybridizes under high stringency to an normal human interleukin-2 gene and thus, would be able to make and use the claimed polypeptides. Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 U.S.C. 112, second paragraph- alleged indefiniteness

The Examiner rejected claims 18-20 and 37-38, alleging that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that claim 18 is vague and indefinite in reciting "is a modification of the natural human interleukin-2," alleging that the metes and bounds of "modification" are not clear because it encompasses substitutions, deletions and combinations.

In response, applicants respectfully traverse the Examiner's above rejection. Applicants contend that the term "modification" is clear, especially when read in conjunction with the phrase "the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene." Accordingly, while the modifications may encompass those suggested by the Examiner, the modified amino acid sequence must still be one which is encoded by a gene which can hybridize under stringent wash conditions to a normal human interleukin-2 gene. Accordingly, applicants contend that the metes and bounds of the claim are clear.

The Examiner also stated that there is insufficient antecedent basis on claim 18 for the phrase "the natural human interleukin-2."

In response, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended claim 18 such that it now recites "normal human interleukin-2."

The Examiner stated that claims 19-20 are vague and indefinite with respect to the term "derived." The Examiner also alleged that the term "being a modification of the natural human interleukin-2" is incorrect because the claimed interleukin-2 is also naturally occurring.

In response, applicants respectfully traverse the Examiner's above rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have herein amended claims 19-20 to recite "obtainable" instead of "derived." In addition, the claims have been amended to recited "normal" instead of "natural."

Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

In view of the above, each of the presently pending claims (i.e. claims 18-20 and 37-38) in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicants believe that no fees, other than the \$55.00 fee for a one month extension of time for a small entity, are due at this time. Authorization is hereby given to charge this amount to the Deposit Account No. 18-1945 under Order No. PBLI-P08-005. In addition, the Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. PBLI-P08-005.

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Respectfully submitted,

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**Exhibit A**

On page 18, lines 8-11, please amend the paragraph as follows.

--Plasmid pHu-IFN- $\alpha$ 001 is deposited with the American Type Culture Collection (ATCC) at [12301 Parklawn Drive, Rockville, MD 20852] 10801 University Boulevard, Manassas, VA 20110-2209; Accession No. [\_\_\_\_] 69640; Deposit date June 7, 1994; and designated as plasmid pHu-IFN- $\alpha$ 001 (E. coli DH5 $\alpha$  pHu-IFN- $\alpha$ 001 as the host vector system).--

**Exhibit B**

--18. (2X Amended) A purified or recombinantly produced polypeptide comprising an amino acid sequence of human interleukin-2 encoded by a gene from a diseased cell, which amino acid sequence is a modification of [the] an amino acid sequence of a [natural] normal human interleukin-2, wherein the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene.--

--19. (Amended) The purified or recombinantly produced polypeptide of [Claim] claim 18, wherein [said] the diseased cell[s are derived] is obtainable from a leukemic leukocyte[s].--

--20. (Amended) The purified or recombinantly produced polypeptide of [Claim] claim 18, wherein [said] the diseased cell[s are derived] is obtainable from human malignancies.--

--37. (Amended) The polypeptide of claim 18, which polypeptide exhibits [one of] either antiviral activity, growth inhibition activity [and] or immunosuppressive activity.--

--38. (Amended) The polypeptide of claim 18, which polypeptide is purified [o ] to homogeneity.--